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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,478	06/07/1999	PHILIP E BRANTON	50013/002003	8679

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KRISTINA BIEKER BRADY
CLARK & ELBING
176 FEDERAL STREET
BOSTON, MA 02110

EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/03/2002 23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/214,478	Applicant(s) BRANTON ET AL.	
	Examiner Shin-Lin Chen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-63,81,85-88,92,93,99 and 100* is/are pending in the application.

4a) Of the above claim(s) *61-63* is/are withdrawn from consideration.

5)☒ Claim(s) *81 and 85-87* is/are allowed.

6)☒ Claim(s) *88,92,93,95,99 and 100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' amendments filed 2-4-02 and 6-4-02 have been entered. The finality of the Official action mailed 10-3-01 (paper No. 16) has been withdrawn. Claims 82-84, 89-91, 94 and 96-98 have been canceled. Claims 81, 85-88, 92, 93, 95, 99 and 100 have been amended. Claims 61-63, 81, 85-88, 92, 93, 95, 99 and 100 are pending and claims 81, 85-88, 92, 93, 95, 99 and 100 under consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 88, 92, 95 and 99 are rejected under 35 U.S.C. 102(e) as being anticipated by Kovesdi et al., 1999 (US Patent No. 5,994,106).

Claims 88, 92, 95 and 99 are directed to an expression vector comprising nucleic acid sequence encoding SEQ ID No. 4 (E4orf4) and capable of inducing apoptosis, wherein said nucleic acid is operably linked to a heterologous inducible, constitutive, or cell-type specific regulatory sequence, and a pharmaceutical composition comprising said expression vector and a pharmaceutically acceptable carrier.

Kovesdi teaches generation of a complementing cell line comprising a multiply deficient adenoviral vector lacking expression of E1, E2, E3, and E4 regions or any specific region of the adenoviral genome and said complementing cell line can complement gene functions at those regions by appropriate expression via expression system having inducible promoters, such as sheep metallothionine, bacterial lac operon, and tetracycline operon, operably linked to E4 region, for example (e.g. column 7, 8). Kovesdi discloses generation of a vector pSMT(sheep metallothionine promoter)/E4 comprising E4 region of adenoviral genome and transfection of cell line 293 with said vector to produce a complementing cell line expressing E4 gene functions (e.g. column 15). The E4 region of adenoviral genome comprises the sequence of SEQ ID No. 4. The buffer solution containing the expression vector pSMT/E4 is considered a pharmaceutically acceptable carrier. Thus, claims 88, 92, 95 and 99 are anticipated by Kovesdi.

It should be noted that the function of the polypeptide comprising SEQ ID No. 4 capable of inducing apoptosis does not carry weight in 102(e) or 103(a) rejection of a product claim and

the function of E4orf4 polypeptide (SEQ ID No. 4) is inherent to the E4 region of the adenoviral genome.

3. Claims 88, 92, 93, 95, 99 and 100 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallenbeck et al., (US Patent No. 5,998,205).

Claims 88, 92, 93, 95, 99 and 100 are directed to an expression vector comprising nucleic acid sequence encoding SEQ ID No. 4 (E4orf4) and capable of inducing apoptosis, wherein said nucleic acid is operably linked to a heterologous inducible, constitutive, or cell-type specific regulatory sequence, and a pharmaceutical composition comprising said expression vector and a pharmaceutically acceptable carrier. Claims 93 and 100 specify the nucleic acid is an adenoviral vector or a retroviral vector.

Hallenbeck teaches a tissue-specific replication-conditional adenoviral vector comprising a heterologous tissue-specific regulatory sequence operably linked to E4 coding region of the adenoviral genome. The E4 region of adenoviral genome comprises the sequence of SEQ ID No. 4. The buffer solution containing the tissue-specific replication-conditional adenoviral vector is considered a pharmaceutically acceptable carrier. Thus, claims 88, 92, 93, 95, 99 and 100 are anticipated by Hallenbeck.

Conclusion

Claims 88, 92, 93, 95, 99 and 100 are rejected. Claims 81 and 85-87 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER

Shin-Lin Chen, Ph.D.